538,915

PCT/MX2003/000093

Translation

PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference SOPH.PCT/003	FOR FURTHER ACTION	See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)
International application No. PCT/MX2003/000093	International filing date (*day/month/year*) 30 October 2003 (30.10.2003)	Priority date (*day/month/year*) 13 December 2002 (13.12.2002)
International Patent Classification (IPC) or national classification and IPC A61K 31/7004, 9/08		
Applicant JIMENEZ BAYARDO, Arturo		

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.

2. This REPORT consists of a total of 5 sheets, including this cover sheet.

☒ This report is also accompanied by ANNEXES, i.e., sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

These annexes consist of a total of 3 sheets.

3. This report contains indications relating to the following items:

- I ☒ Basis of the report
- II ☐ Priority
- III ☒ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- IV ☐ Lack of unity of invention
- V ☒ Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- VI ☐ Certain documents cited
- VII ☐ Certain defects in the international application
- VIII ☐ Certain observations on the international application

Date of submission of the demand	Date of completion of this report
05 October 2004 (05.10.2004)	17 February 2005 (17.02.2005)
Name and mailing address of the IPEA/ES	Authorized officer
Facsimile No.	Telephone No.

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.
PCT/MX2003/000093

I. Basis of the report

1. With regard to the **elements** of the international application:*

☐ the international application as originally filed

☒ the description:

pages 1 - 11, as originally filed
pages _____, filed with the demand
pages _____, filed with the letter of _____

☒ the claims:

pages _____, as originally filed
pages _____, as amended (together with any statement under Article 19
pages _____, filed with the demand
pages 12 - 14, filed with the letter of 09 February 2005 (09.02.2005)

☒ the drawings:

pages 16 - 19, as originally filed
pages _____, filed with the demand
pages _____, filed with the letter of _____

☐ the sequence listing part of the description:

pages _____, as originally filed
pages _____, filed with the demand
pages _____, filed with the letter of _____

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.
These elements were available or furnished to this Authority in the following language _____ which is:

☐ the language of a translation furnished for the purposes of international search (under Rule 23.1(b)).
☐ the language of publication of the international application (under Rule 48.3(b)).
☐ the language of the translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

☐ contained in the international application in written form.
☐ filed together with the international application in computer readable form.
☐ furnished subsequently to this Authority in written form.
☐ furnished subsequently to this Authority in computer readable form.
☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. ☐ The amendments have resulted in the cancellation of:

☐ the description, pages _____
☐ the claims, Nos. _____
☐ the drawings, sheets/fig _____

5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).**

* *Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rule 70.16 and 70.17).*

** *Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.*

Supplemental Box
(To be used when the space in any of the preceding boxes is not sufficient)

Continuation of: III.1

Claims 8 to 12 relate to subject matter which, in the opinion of this Authority, is subject to the provisions of PCT Rule 67.1(iv), concerning methods for the treatment of the human or animal body by surgery or therapy. Consequently no opinion on the industrial applicability of the subject matter of these claims will be established (PCT Article 34(4)(a)).

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.
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V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Claims	1-17	YES
	Claims		NO
Inventive step (IS)	Claims	1-17	YES
	Claims		NO
Industrial applicability (IA)	Claims	1-7, 13-17	YES
	Claims		NO

2. Citations and explanations (Rule 70.7)

Document	Publication or identification no.	Publication date
D01	ES 2067418 A	16 March 1995
D02	WO 9718835A	29 May 1997
D03	WO 0051620 A	8 September 2000
D04	EP 868909 A	07 October 1998

The present invention concerns an intravitreally injectable solution for treating vitreous haemorrhages which comprises an active ingredient, mannitol, and a carrier solution (Sophisen), which comprises polyoxylic stearate, dehydrated disodium edate, sodium chloride, boric acid, sorbic acid, sodium bisulphite and distilled water. The invention also concerns the method for preparing this solution.

Document D1 concerns the use of human recombinant interleukin-1 beta in the production of medicaments for treating human intravitreal haemorrhages in the form of intravitreal injections which are intended to be administered transconjunctivally.

Document D2 concerns the use of enzymes for eliminating vitreal haemorrhaging. These enzymes are in the form of a liquid solution which is injected into the vitreous humour.

Document D3 concerns methods for treating ocular disorders, including the acceleration of the elimination of blood from the vitreous humour. Urea, urea derivatives, non-steroid anti-inflammatories, etc. are applied by means of intravitreal injection.

Document D4 uses the same carrier means as the application, together with various therapeutic agents for topical ophthalmic application.

Therefore, none of the citations discloses mannitol as active ingredient together with the carrier solution whose composition is described in claim 1. The subject matter of claims 1 to 17 is thus considered to meet the novelty and inventive step requirements (PCT Article 33(2) and (3)).

Finally, the subject matter of claims 1 to 7 and 13 to 17 is considered to meet the industrial applicability requirements as defined in PCT Article 33(4). The PCT Contracting States have no uniform criteria as concerns the industrial applicability of claims 8 to 12. Patentability may also depend on the wording of the claims.